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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/864,373 05/25/2001 William F. Krise KRISE 1A . 1608 7590 03/11/2004 **EXAMINER** Office of Counsel Code OC4 PADMANABHAN, KARTIC Naval Surface Warfare Center ART UNIT Indian Head Division PAPER NUMBER 101 Strauss Ave., Bldg. D-326 1641 Indian Head, MD 20640-5035

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | |
|--|--|-----------------|--|---------|--|
| Office Action Summary | | 09/864,373 | KRISE ET AL. | | |
| | | Examiner | Art Unit | | |
| | | Kartic Padmanab | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ | Responsive to communication(s) filed on <u>03 December 2003</u> . | | | | |
| <i>'</i> — | , | · | | | |
| 3)□ | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>7-12,15 and 16</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) 16 is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>7-12 and 15</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) 7-12,15 and 16 are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10)⊠ The drawing(s) filed on <u>6/18/02</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Gee the attached detailed Office action for a list of the certified copies not received. | | | | | |
| | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | |
| | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB | ┌┐ . | Paper No(s)/Mail Date Notice of Informal Patent Application (PT | ΓΟ-152) | |
| | er No(s)/Mail Date | | Other: | • | |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, claims 7-12 and 15, in Paper No. 11 is acknowledged.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 7-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 4. Claim 7 is rejected as vague and indefinite for the recitation of a light source comprising near infrared light emissions. A light source may emit certain emissions, but it does not comprise those light emissions. In addition, the term "near" in claim 7 is a relative term which renders the claim indefinite. The term "near" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- 5. Claims 7 is also rejected as vague and indefinite for the recitation of an activated matrix and analysis target area because it is unclear if these components are a part of the sample holder as a whole or are part of the uptake channel portion of the sample holder.
- 6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural

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cooperative relationships are the way in which all the recited components of the device function in order to detect a molecule, which is the purpose of the claimed device.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 7, 9-12, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Giebeler et al. (US Pat. 6,236,456 B1). The reference discloses an optical system comprising a light source which may be a lamp or laser. The light passes through a filter wheel comprising a plurality of filters, which filters may be bandpass filters. The sample holder of the reference may be a cuvette or a multi-assay plate well. In the event of a multi-well plate, the plate as a whole is interpreted as the sample holder, and the individual wells are tubes which reduce the diameter of the sample holder. Although mirrors are preferred, the device of the reference may also comprise a fiber optic lens. In one embodiment, the detector of the reference may be a photodiode. The device may also include an LCD readout. Further, when the target analysis area enters the reading chamber via the housing door, the enclosed analysis area/physical barrier limitation of claim 11 is deemed met. Before entry into this reading area, the sample holder that is not enclosed/free of solid phase of claim 12 is deemed met.
- 9. Claims 7-9, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Pat. 5804,451). The reference discloses an optical system, wherein a laser diode may

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be used as the light source. The apparatus may also comprise a bandpass filter as the filter means, as well as a fiber optic lens. A single channel or multi-channel detector may also be employed with the reference. The presence of a sample holder is inherent because sample is irradiated in the reference, and the sample has to be held by something for this to occur. Anything that holds or contains sample qualifies as a sample holder. The configuration of the reference, wherein a sample is irradiated on an open surface, is sufficient to meet the limitation of claim 12.

10. Claims 7-12 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by

Narayanan (US Pat. 6,593,148 B1). The reference discloses a DNA sequencing apparatus. To

transmit light to the gel sandwich 150, the laser diode assembly 170 includes a housing 210 a

focusing lens 212, a narrow band pass filter 214, a collimating lens 216 and a laser diode 218.

The laser diode 218 emits far red, near infrared, or infrared light which is collimated by the lasercollimating lens 216 and filtered through the narrow band pass filter 214. This light is focused
by the focusing lens 212 onto the gel sandwich 150. The detector includes a light sensor which
is preferably an avalanche photodiode sensitive to the infrared light emission of the marker.

Response to Arguments

- 11. Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive.
- 12. Applicant's arguments that the Wang reference does not teach the use of near infrared light are erroneous. The reference clearly states, "when the sample is prepared from a body fluid such as blood or urine, the Raman excitation light which is applied to the sample is preferably prepared from near infrared light."

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13. Applicant's arguments regarding the portability of the claimed device amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. They also do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. As such, applicant's arguments fail to comply with 37 CFR 1.111(b) and 37 CFR 1.111(c). Applicant has not even addressed the rejection over Giebeler et al., which the examiner takes an indication of applicant's acceptance that the reference anticipates the claimed invention.

Conclusion

Claims 7-12 and 15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan Patent Examiner Art Unit 1641

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LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

03/08/04